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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,653	07/07/2003	Andrew Kim	90448U	7515
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EXAMINER				
BACHMAN, LINDSEY MICHELLE				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
10/28/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/614,653

**Applicant(s)**

KIM, ANDREW

**Examiner**

LINDSEY BACHMAN

**Art Unit**

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to Applicant's amendment filed 3 June 2008.

#### ***Response to Arguments***

Applicant's arguments regarding the rejection under 35 USC 102(b) under Luscher, have been considered but are not persuasive. Applicant argues that the claims recite "a particular needle structure suitable for use in Applicant's suturing apparatus." This is not persuasive because the only structure regarding the needle in the claims is "an elongated cannulated suturing needle". Clearly the needle provided by Luscher meets this limitation. Further, Applicant argues that the claim specifically recites hydrodynamically propelling a suture. This limitation is only mentioned in the preamble and it does not provide any structural differences that overcome the prior art. See MPEP 2111.02. It is noted that the features upon which applicant relies (i.e., "a particular needle structure suitable for use in Applicant's suturing apparatus") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding Claim 5-7, Applicant argues that the needle includes a leading and trailing edge. The needle of Luscher is beveled in Figure 5, providing both a leading and trailing edge. Regarding the rounded tip, this is taught by Sontag, as discussed in the rejection below.

Regarding Claim 8, Applicant argues that the protector taught by Olovson does not disclose stiffening means. This is not persuasive because the protector inherently stiffens the needle because it provides an extra layer over the outer surface of the needle. Further, the claim does not state whether the stiffening cover is intended to stiffen the needle during use or during storage.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by  
Luscher (US Patent 6,299,590).**

Luscher'590 discloses a device containing a syringe (see Figure 5) containing a barrel (31) and a plunger (32) and a connector (35) capable of being detachably mounted to a needle (17). The barrel is sized and shaped for holding a suture and the fluid used for expelling the suture (column 1, line 45-57). Further, the device contains an elongated cannulated needle (17) (column 4, line 66-67) capable of receiving and releasing a suture (column 4, line 55-67). The distal end of the needle (4) can have a sharp distal point (see Figure 5) and is configured to receive a suture extending from the lumen of the needle.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luscher'590.**

Claims 2-4: Luscher'590 does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

**Claim 5-7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luscher'590, as applied to Claim 1, in further view of Sontag (US Patent 5,236,443).**

Luscher'590 teaches the limitations of Claim 5 except for a rounded tip of a suture needle.

Sontag'443 teaches a suturing with openings at the end that are slightly rounded to protect the surgeon from accidental cuts or punctures (column 4, lines 15-21). It would have been obvious to one skilled in the art at the time the invention was made to use rounded needles in order to protect the user from accidental cuts.

Claims 6-7: Luscher'590 does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

**Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luscher'590, as applied to Claim 1, in further view of Olovson (US Patent 6,702,786).**

Luscher'590 teaches the limitations of Claim 8 except for a stiffening cover of the needle.

Olovson teaches a syringe with a stiffening cover (2) over a needle (14) in order to protect the needle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Luscher'590 with a stiff cover, as taught by Olovson, in order to protect the needle.

**Claim 1, 9-14 are rejected under Casperi et al. (US Patent 4,890,615) in view of Weng (US patent 5,569,270).**

Claim 1, 9, 11, 12, 14: Casperi teaches the use of a suturing device with a pair of jaws (34, 44), a proximal lever to operate the jaws (24, 26), and a lumen (36 is a tubular member) extending from the proximal end to distal end for passage of a needle (56).

The needle expels the suture from its tip (column 5, lines 13-17). Caspari does not teach that the suture distributor is a syringe. The needle of Caspari is beveled and therefore has a leading and trailing edge.

Weng'270 teaches a suturing device that includes an elongate needle (46) having a lumen extending from the proximal end to the distal end that is capable of passing a suture (column 2, lines 45-60). The device also contains a barrel (24, column 4, lines 44-46) and plunger (32) and a connector (58). Suture material is introduced into the needle (column 2, lines 54-56 and column 3, lines 55-63). Liquid fills the barrel, the needle is passed through the tissue to be sutured and the suture is expelled with the force of the liquid flow (column 2, lines 45-60). Weng'270 discloses a stiffening cover (60) that covers most of the needle (see Figure 1). It would have been obvious to modify the suture distributor taught by Caspari with the suture distributor taught by Weng'270 because it would be obvious to apply a known technique to a known device ready for improvement in order to yield predictable results.

Claim 10, 13: Caspari in view of Weng does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

**Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weng'270 in view of Christy (US patent 5,350,385).**

Claim 15, 17, 18: Weng'270 teaches a method of suturing with a suturing device that includes an elongate curved needle (46) having a lumen extending from the

proximal end to the distal end that is capable of passing a suture (column 2, lines 45-60). The device also contains a barrel (24, column 4, lines 44-46) and plunger (32) and a connector (58). Suture material is introduced into the needle (column 2, lines 54-56 and column 3, lines 55-63). Liquid fills the barrel, the needle is passed through the tissue to be sutured and the suture is expelled with the force of the liquid flow (column 2, lines 45-60). Weng'270 discloses a stiffening cover (60) that covers most of the needle (see Figure 1).

Weng'270 does not disclose folding the suture over the end of the suture. However, it is old and well known to fold a suture back over a needle when performing a suturing operation, as taught by Christy, in order to smoothly insert both ends of the suture into the tissue. It would have been obvious to modify the method of Weng as taught by Christy so that it too has this advantage.

Claim 16: Weng'270 does not disclose introducing the suture into the barrel with drawing liquid into the barrel at the same time as the suture. However, it is old and well known to draw things into syringes via the suction provided by the plunger. It would be obvious to one of ordinary skill in the art to try drawing the suture into the syringe because choosing from a finite number of identified predictable solutions would have a reasonable expectation of success. Further, it is old and well known to apply a known technique to a known device to yield predictable results.

**Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weng'270 in view of Christy'385, as applied to Claim 15, in further view of Caspari.**

Claim 19, 20: Weng'270 in view of Christy'385 teaches the limitations of Claim 19 and 20 except for a pair of jaws directing the needle and suture.

Caspari teaches the use of a suturing device with a pair of jaws (34, 44), a proximal lever to operate the jaws (24, 26), and a lumen (36 is a tubular member) extending from the proximal end to distal end for passage of a needle (56). The needle expels the suture from its tip (column 5, lines 13-17). It would have been obvious to modify the method of Weng'270 by combining Weng'270's tool with Caspari in order to increase the amount of control over the suturing operation and also increase the functionality of the device.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./  
Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773